UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NANCY GAGNON, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. ALKERMES PLC, RICHARD F. POPS and JAMES M. FRATES, Defendants.	Civil Action No. 1:17-cv-09178-WHP CLASS ACTION SECOND AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS JURY TRIAL DEMANDED

TABLE OF CONTENTS

Page

Page

Lead Plaintiff Local 731 I.B. of T. Private Scavenger and Garage Attendants Pension Trust Fund ("Plaintiff" or "Lead Plaintiff"), individually and on behalf of all others similarly situated, by its undersigned attorneys, alleges the following based upon the investigation of its counsel, which included a review of United States Securities and Exchange Commission ("SEC") filings made by Alkermes plc ("Alkermes" or the "Company"), as well as securities analysts' reports and advisories, press releases, media reports and other public statements issued by or about the Company, conversations with reporters and researchers, and a review of over 1,900 pages of documents produced in response to a Freedom of Information Act ("FOIA") request to the U.S. Food and Drug Administration ("FDA"). Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all persons other than Defendants (defined below) who purchased or otherwise acquired Alkermes common stock between February 24, 2015 and November 14, 2017, inclusive (the "Class Period"), against Alkermes and certain of its officers and directors for violations of the federal securities laws. Plaintiff brings this action seeking to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Vivitrol, which is sold by Alkermes, is an injectable extended-release version of naltrexone, an opioid dependence medicine. After years of middling sales, revenues from Vivitrol began rapidly increasing beginning in 2015. This made Vivitrol the single most important product in Alkermes' sales portfolio during the Class Period.

3. Defendants achieved this substantial growth in Vivitrol sales through a fraudulent and deceptive marketing campaign that was years in the making. Naltrexone has been on the market since the 1980s but was sparsely used by the medical community to treat opioid dependence because it requires patients to detoxify before beginning treatment and only provides short windows of relief

from opioid cravings. Understanding that naltrexone was perceived by the medical community to have limited utility, Defendants focused their marketing efforts instead directly on policymakers, including drug courts, prison wardens, law enforcement professionals, and other similar groups, all of whom lack sophisticated medical training.

4. Defendants informed investors that they were pursuing this non-medical market for Vivitrol, but misleadingly characterized this market's rapidly increased adoption of Vivitrol as organic and self-propagating. In reality, this market only began purchasing large quantities of Vivitrol after a sustained campaign by Defendants to convince these non-medical entities that the leading treatment options for opioid dependence – methadone and Suboxone – were ineffective because they contain opioids, even though this contradicted scientific data supporting the use of methadone and Suboxone as treatments and Alkermes lacked scientific evidence establishing Vivitrol as a better treatment option.

5. At the same time that Defendants were misleading investors about the real driver behind Vivitrol's rapid sales growth, Defendants also misled investors about the effectiveness of Vivitrol as a treatment option. Specifically, Defendants claimed that patients using Vivitrol would not relapse to opioid use in the 28-day time period after patients received their Vivitrol shots. But, at the time they made these statements, Defendants had access to clinical trial data that found up to 30% of Vivitrol patients relapsed between the first and second shots, meaning these statements were untrue. In addition, Defendants falsely claimed that only Vivitrol, and not methadone or Suboxone, could lead to a drug-free life for addicts. Defendants lacked a reasonable basis for these statements because the Company had no scientific data to support this claim.

6. Investors began to learn that the Company's Class Period disclosures concerning Vivitrol were false and misleading through a series of news exposés beginning in June 2017 that

revealed the Company's deceptive marketing practices and that Vivitrol users frequently relapse within 28 days after receiving their first shot. Further corrective disclosures followed when the Company announced: (i) its receipt of a subpoena related to Vivitrol; (ii) an investigation by U.S. Senator Kamala Harris (D-CA) into Alkermes' deceptive marketing practices for Vivitrol; and (iii) the results of two studies comparing Vivitrol to Suboxone, both of which showed that Vivitrol was, at best, only equally as effective as Suboxone at treating opioid dependence. Following each of these adverse disclosures, Alkermes' stock price declined, causing losses to its investors.

7. At all relevant times during the Class Period, the Individual Defendants (defined below) were personally motivated to conceal the Company's deceptive marketing practices and Vivitrol's limitations from Alkermes' investors. Specifically, before the disclosure of the adverse information withheld from Alkermes' investors, the Individual Defendants took advantage of the artificial inflation in the price of Alkermes stock and sold between ***12% and 26%*** of their personally-held shares of Alkermes stock for gross proceeds ***in excess of $40 million***.

JURISDICTION AND VENUE

8. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and Section 27 of the Exchange Act.

10. Venue is proper in this Judicial District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b). Alkermes' stock trades on the NASDAQ, located within this District.

11. In connection with the acts, conduct and other wrongs alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not

limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

12. Lead Plaintiff purchased Alkermes securities during the Class Period as set forth in its previously filed certification, which is incorporated by reference herein, and was damaged thereby.

13. Defendant Alkermes plc is incorporated in Ireland, although its functional headquarters are in Waltham, Massachusetts. Alkermes lists its common stock on the NASDAQ under the ticker symbol "ALKS."

14. Defendant Richard F. Pops ("Pops") has served as Alkermes' Chief Executive Officer ("CEO") since he joined the Company in 1991. Alkermes was a private company consisting of just 25 employees when defendant Pops first became CEO. Defendant Pops has been a director of Alkermes since 1991, and has been Chairman of the Company's board of directors since April 2007. Defendant Pops signed the Company's annual and quarterly reports, filed on Forms 10-K and 10-Q, respectively, during the Class Period. Defendant Pops received a B.A. in Economics in 1983 and has no formal medical training or education. During the Class Period, defendant Pops sold over 500,000 shares of Alkermes stock for proceeds of over $28 million, at times and in amounts that were unusual.

15. Defendant James M. Frates ("Frates") has served as Alkermes' Chief Financial Officer ("CFO") since he was hired by the Company in 1998. Defendant Frates signed the Company's annual and quarterly reports, filed on Forms 10-K and 10-Q, respectively, during the Class Period. Defendant Frates received a B.A. in Government and an M.B.A. in 1996 and has no formal medical training or education. During the Class Period, defendant Frates sold over 210,000 shares of Alkermes stock for proceeds of over $12 million, at times and in amounts that were unusual.

16. The defendants referenced above in ¶¶14-15 are sometimes referred to herein as the "Individual Defendants."

17. The defendants referenced above in ¶¶13-15 are collectively referred to herein as "Defendants."

18. The Individual Defendants possessed the power and authority to control the contents of Alkermes' SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of the Company's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with the Company, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

19. Defendants are liable as direct participants in the wrongs complained of herein. In addition, Defendants were "controlling persons" within the meaning of Section 20(a) of the Exchange Act and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of their positions of control, Defendants were able to and did, directly or indirectly, control the conduct of Alkermes' business.

20. Defendants, because of their positions with the Company, controlled and/or possessed the authority to control the contents of Alkermes' reports, press releases and presentations to securities analysts and through them, to the investing public. Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading, prior to or shortly after

their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Thus, Defendants had the opportunity to commit the fraudulent acts alleged herein.

21. As controlling persons of a publicly-traded company whose stock was registered with the SEC pursuant to the Exchange Act, and was traded on the NASDAQ and governed by the federal securities laws, Defendants had a duty to promptly disseminate accurate and truthful information with respect to Alkermes' financial condition and performance, growth, operations, financial statements, business, products, markets, management, earnings and present and future business prospects, and to correct any previously issued statements that had become materially misleading or untrue, so that the market prices of Alkermes common stock would be based upon truthful and accurate information. Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

22. Each of the Defendants is liable as a participant in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Alkermes common stock by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme deceived the investing public regarding Alkermes' business, operations, and the intrinsic value of Alkermes' common stock, causing Plaintiff and other members of the Class to purchase Alkermes common stock at artificially inflated prices.

SUBSTANTIVE ALLEGATIONS

Alkermes Reformulates Naltrexone into Vivitrol

23. Naltrexone is a medicine that is used to treat opioid and alcohol dependence by blocking their effect on the brain when users take these substances. Specifically, naltrexone competes for the receptors in the brain that cause the positive feeling, or high, associated with opioids and alcohol. Naltrexone does not provide a complete blockage; ingesting significant amounts of opioids or alcohol can overcome this receptor blockade.

24. Naltrexone was originally designed by E. I. du Pont de Nemours and Company ("DuPont") as a pill to be taken orally once daily. Under this formulation, naltrexone was approved by the FDA for the oral treatment of opioid dependence in 1984 under the brand name Trexan. Naltrexone was exclusive to DuPont until 1992, when DuPont's patent for naltrexone lapsed and generic versions of the medicine became available.

25. By 1995, annual sales of Trexan reached between $5 million and $8 million. During this time, Trexan was being used by approximately 15,000-25,000 patients, representing around 5% of heroin addicts at the time. That same year, DuPont received FDA approval to use oral naltrexone to treat alcohol dependence under the brand name ReVia.

26. Ultimately, Trexan proved to have limited utility in treating opioid addiction. Oral naltrexone is a poor treatment for opioid dependence because it requires detoxification before usage, which is a significant barrier given the immense difficulty addicts have in achieving abstinence on their own. For the subset of opioid addicts who are able to detox, oral naltrexone still presents treatment challenges because it has to be administered daily, meaning that an addict who is overwhelmed by cravings can easily withdraw from treatment by skipping his or her next daily dose of naltrexone. These factors relegated oral naltrexone to being a fringe treatment that had very limited utility.

27. After many years of oral naltrexone having a limited impact on treating opioid dependence, Alkermes sought to rectify the limitations of oral naltrexone by developing Vivitrol, which is an extended-release formulation of naltrexone that is administered once every 28 days through an injection into a patient's muscle. Once administered, Vivitrol provides a steady dosage of 28 days-worth of naltrexone to patients. As with oral naltrexone, opioid addicts can only take Vivitrol once they have detoxed for seven to ten days.

28. Initially, Alkermes was only able to obtain FDA approval for Vivitrol to treat alcohol dependence. This was achieved in 2006. It took another four years for Alkermes to obtain FDA approval for Vivitrol for opioid dependence, which occurred in 2010.

29. Following this approval, the market for Vivitrol among physicians and other medical professionals was very limited given oral naltrexone's long history of having limited efficacy in treating opioid dependence.

After Years of Irrelevance, Vivitrol Suddenly Becomes Alkermes' Most Important Drug

30. According to the 2016 Form 10-K, Alkermes generates revenue in two ways: (i) through direct sales of its proprietary drugs; and (ii) indirectly through sales of drugs that utilize Alkermes' proprietary technologies.

31. During the Class Period, Alkermes only had two proprietary drugs: (i) Vivitrol; and (ii) Aristada, which did not receive FDA approval until October 2015. Of the two, Vivitrol represented a far greater percentage of Alkermes' revenues during the Class Period.

32. Before the Class Period, for the reasons described above in ¶¶25-29, the Company derived limited revenue from Vivitrol, as the bulk of the Company's revenues came from selling drugs that utilized the Company's proprietary technologies. The Company's investor presentations from 2011 until the beginning of the Class Period did not even include a discussion of Vivitrol because its history of limited effectiveness in treating opioid dependence relegated it to a very small market share. Thus, prior to 2015, Vivitrol was immaterial to Alkermes' investors.

33. That all changed once the Class Period began. Following the receipt of FDA approval for Vivitrol in 2010, Alkermes recognized that it had to dramatically alter the marketing approach behind Vivitrol. Rather than acknowledge that Vivitrol was only appropriate for the subset of opioid addicts who are able to successfully detox, as the medical community understood for

naltrexone, Alkermes embarked on a campaign to circumvent the normal market for such treatment and began peddling Vivitrol directly to policymakers, drug courts,[1] prison wardens, law enforcement professionals, and other similar groups that lacked formal medical education.

34. This campaign centered on deceptive and misleading marketing efforts by Alkermes to convince this unconventional market that other established opioid dependence treatments were less effective as compared to Vivitrol, despite having no scientific proof to back up these claims. Defendants began engaging in this campaign concomitantly with Vivitrol receiving FDA approval in 2010.

35. These efforts did not begin paying off for the Company until the beginning of the Class Period, when sales of Vivitrol suddenly began to sharply increase. For example, during an analyst and investor conference call on February 24, 2015, defendant Frates stated that "[f]or Vivitrol, ***the fourth quarter was our strongest quarter yet***, with net sales of $29.7 million compared to $20.6 million for the same period last year, ***demonstrating growth of 44% versus last year*** and 15% sequentially."[2]

36. Vivitrol sales continued to steadily increase during the Class Period, with defendant Frates noting on an analyst and investor conference call on July 30, 2015, that "[t]oday***, we are also improving our financial guidance for 2015, based primarily on the solid growth we have seen in Vivitrol net sales***. . . . Vivitrol had a strong quarter, with net sales of $37.2 million, compared to $21.6 million for the same period last year, ***demonstrating growth of 72%***."

37. As the Class Period continued, Vivitrol sales were the single most important factor in driving revenue growth at the Company. In Alkermes' February 25, 2016 press release, which was

[1] Drug courts are specialized court docket programs that target criminals who have drug dependency problems and seek to help these individuals achieve long-term recovery.

[2] All emphasis is added unless otherwise stated.

filed on Form 8-K with the SEC, Defendants acknowledged this, stating, in pertinent part, as follows:

> ***Our financial results in 2015 were driven by the strong performance of VIVITROL***, the approval and launch of ARISTADA into a rapidly growing long-acting antipsychotic market, and the continued strength of our base business," commented James Frates, Chief Financial Officer of Alkermes. "In 2016, we expect our business to continue to grow, led by VIVITROL and ARISTADA. Together with our solid royalty and manufacturing base business, ***these proprietary products are expected to drive revenue growth of 15 to 20 percent***."

38. Similarly, in Alkermes' February 15, 2017 press release, which was filed on Form 8-K with the SEC, the Company stated, in pertinent part, as follows:

> "Our 2016 financial results reflect the strong growth of our proprietary commercial products and demonstrate the power and breadth of the Alkermes business," commented James Frates, Chief Financial Officer of Alkermes. "We enter 2017 in a strong financial position and ***expect total revenues to grow approximately 20%, driven by the robust volume growth of VIVITROL***® and ARISTADA®. In 2017, we are making additional investments that will drive the future growth of Alkermes, including in our development pipeline, the commercial organization for ALKS 5461 and ***expanded VIVITROL manufacturing capabilities to support expected demand into the 2020s***."

39. During the Class Period, Vivitrol sales represented a significant portion of Alkermes' total revenues. Specifically, Vivitrol sales were between 15.2% and 31% of Alkermes' total revenues during the Class Period. Vivitrol sales consistently represented over 20% of Alkermes' total revenues beginning with the second fiscal quarter of 2015 (the period from April 1, 2015 to June 30, 2015) and consistently represented over 30% of Alkermes' total revenues beginning with the first fiscal quarter of 2017 (the period from January 1, 2017 to March 31, 2017).

40. As a result, unlike in the time period between Alkermes receiving FDA approval for using Vivitrol to treat opioid dependence (2010) and the beginning of the Class Period (early 2015), during the Class Period, Vivitrol was the Company's most significant revenue driver. However, as explained below in ¶¶43-60, Defendants were forced to resort to fraudulent schemes in order to achieve this growth given that the medical community was well-versed in the limitations of

naltrexone in treating opioid dependence. Specifically, to drive growth for Vivitrol, Defendants focused on the non-medical market and resorted to misinforming it about the efficacy of other opioid dependence treatments to make Vivitrol appear superior, even though Defendants lacked a scientific basis for such claims. In turn, during the Class Period, Defendants made numerous false and misleading statements and failed to disclose material information to investors about the true nature of the Company's marketing efforts for Vivitrol.

41. As explained above in ¶¶35-40, these efforts paid off in spades for Defendants. Indeed, by September 2016, Alkermes devoted an entire investor day to discussing Vivitrol and its future potential, and by February 2017, shortly before the 2016 Form 10-K was filed, Alkermes reported that Vivitrol net sales grew in fiscal year 2016 by 45% to $209 million. This reflected robust growth, especially considering that net sales for Vivitrol in fiscal year 2011 were only $28.9 million.

42. Accordingly, Vivitrol was the single most important component of Alkermes' financial portfolio during the Class Period, and its significance to Alkermes only increased as the Class Period continued. Thus, Defendants undoubtedly knew, or recklessly disregarded, relevant information concerning Vivitrol during the Class Period given its centrality to Alkermes' financial success.

Alkermes Deceptively Markets Vivitrol
Before and During the Class Period

43. Even though naltrexone has been around since 1984 and its limitations were well understood by the medical community, Alkermes has successfully developed a market for Vivitrol by focusing on the non-medical policymaker community, including drug courts, legislators, and law enforcement. While investors knew that Alkermes was targeting this non-medical market, they did

not know that Defendants' deceptive and misleading marketing efforts for Vivitrol were the driving force behind the Company's growth.

44. Alkermes targeted this non-medical market because it lacks a sophisticated understanding of treating opioid addiction, making these entities and individuals prime candidates for blindly accepting misleading information about Vivitrol's efficacy as compared to the established treatments for opioid addiction – methadone and Suboxone (which is the brand name of buprenorphine).

45. Methadone and buprenorphine are considered agonist treatments, meaning that they contain opioids which trigger the opioid receptors in the brain, delivering a mild effect and tricking the brain into thinking it is receiving the abused opioid, while preventing patients from feeling the euphoria that opioid users experience. These treatments reduce cravings and prevent patients from experiencing withdrawal symptoms, allowing them to slowly wean off of opioids and ultimately achieve abstinence.

46. Unlike with Vivitrol, addicts who take methadone and buprenorphine are not required to endure the tormenting process of detoxing before beginning treatment, which means they can immediately begin treatment once they receive a prescription. Methadone and buprenorphine enable their users to control cravings, withdrawal symptoms, and the feeling of physical dependency to opioids. For these reasons, methadone and buprenorphine have long-standing reputations as the gold-standard treatment options among the medical community for treating opioid dependence.

47. Before and during the Class Period, Alkermes had not conducted a single study comparing the effectiveness of Vivitrol to methadone or Suboxone. In addition, no independent studies were conducted comparing these treatments during this time period.

48. Despite lacking any scientific basis for promoting Vivitrol over methadone and Suboxone, before and during the Class Period, Defendants engaged in a calculated campaign to mislead the policymaker community, including drug courts, legislators, and law enforcement, into believing that Vivitrol was more effective than the other treatments because it contains no opioids.

49. As part of this campaign, before and during the Class Period, Alkermes and its lobbyists circulated misleading information concerning methadone and Suboxone. Specifically, according to an article published by NPR on Alkermes' deceptive Class Period sales practices for Vivitrol, dated June 12, 2017 (the "6/12/17 Article"):[3]

> ***[Alkermes] circulated a [white paper], obtained by NPR and Side Effects, that presented slanted material about [Suboxone], focused on the drug's potential for diversion and abuse while largely ignoring its benefits for individuals and for public health***. "This is basically a very long attempt to bash [Suboxone]," said [Basia] Andraka-Christou [a researcher at the Fairbanks School of Public Health in Indianapolis] when we showed her the documents.

50. Defendants were fully aware of the existence and contents of this document. Specifically, the 6/12/17 Article states that Matthew Henson ("Henson"), Alkermes' Director of Public Relations from September 2016 to the present, "acknowledged in a phone interview that [Alkermes] circulated the white paper, which he described as a 'working document' meant to educate federal lawmakers about medication-assisted treatment options." Effectively, Henson, who is listed on Alkermes' press releases as being the Company's main media contact, admits that before and during the Class Period Defendants knew about, or recklessly disregarded, Alkermes' misleading tactics to increase Vivitrol sales.

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[3] Jake Harper, *A Drugmaker Tries To Cash In On The Opioid Epidemic, One State Law At A Time*, NPR (June 12, 2017, 8:57 AM), https://www.npr.org/sections/health-shots/2017/06/12/523774660/a-drugmaker-tries-to-cash-in-on-the-opioid-epidemic-one-state-law-at-a-time (last visited May 15, 2018).

51. Likewise, Alkermes' standard pitch to the policymaker community before and during the Class Period, including to drug courts, legislators, and law enforcement, was that methadone and Suboxone are themselves addictive "black market" or "street" drugs that are ineffective for treating opioid dependence and are instead abused like heroin or other opioids.

52. Defendants knew that these claims were untrue and would not pass muster with the medical community. For example, according to a June 11, 2017 interview in *The New York Times* (the "6/11/17 Article"),[4] Dr. Joshua M. Sharfstein, an associate dean at the Johns Hopkins Bloomberg School of Public Health who served as the Secretary of Maryland's Department of Health and Hygiene during the 2011 to 2014 time frame, had to call a meeting with Alkermes during his time as Secretary to tell the Company to "back off talking down methadone and [Suboxone]" to legislators, which had been a part of Alkermes' efforts to lobby Maryland to adopt Vivitrol over these other treatments.

53. Dr. Sharfstein further stated that Alkermes is "exploiting a stigma that exists out of a very narrow view of their own economic self-interest . . . and the result is going to be more people dying if they cannot get access to effective treatment." Dr. Sharfstein's comments establish that Defendants knew, or recklessly disregarded, by the beginning of the Class Period, that their tactics for selling Vivitrol were misleading, unethical, and presented information that was medically inaccurate.

54. In addition, according to Dr. Corey Waller, an addiction specialist who heads legislative advocacy for the American Society of Addiction Medicine ("ASAM"), whose interview by NPR was published in the 6/12/17 Article, "[i]n a number of states, ***there has been a significant***

[4] Abby Goodnough & Kate Zernike, *Seizing on Opioid Crisis, a Drug Maker Lobbies Hard for Its Product*, N.Y. Times (June 11, 2017), https://www.nytimes.com/2017/06/11/health/vivitrol-drug-opioid-addiction.html (last visited May 15, 2018).

push by Alkermes and their lobbyists to really squelch other treatment[s], so that they can get access to bigger markets for their drug."

55. Alkermes' deceptive sales tactics were very successful at misleading the non-medical market. According to an article by STAT, dated June 29, 2017 (the "6/29/17 Article"),[5] a recent survey of criminal justice representatives found that most of them favored Vivitrol over methadone and Suboxone because scientific evidence showed Vivitrol was better. This was an impossible conclusion for these individuals to draw because, as Defendants were well aware, there were no scientific studies in existence at this time that compared Vivitrol to methadone or Suboxone, let alone ones that demonstrated Vivitrol was the more effective treatment. The 6/29/17 Article illustrates the extent to which Alkermes' deceptive marketing campaign was succeeding with this non-medical market.

56. Investors were not apprised of these misleading sales tactics. Instead, throughout the Class Period, Defendants repeatedly represented to investors that the Company engaged in "customary pharmaceutical company practices" in promoting their medications when the opposite was true. In addition, Defendants misleadingly informed investors that Vivitrol's success with the policymaker community, including drug courts, legislators, and law enforcement, was due to "organic growth" and was "self-propagating," when, in reality, its success and proliferation came from Alkermes' misleading and deceptive marketing practices.

57. Defendants' deceptive marketing and zealous lobbying caused Alkermes common stock to trade at artificially high prices, as the revenues recognized from these misleading efforts

[5] Daniel Wolfe, *Vivitrol Offers the Fantasy of Being Drug-Free. but That's Not the Most Important Thing in Tackling Addiction*, STAT (June 29, 2017), https://www.statnews.com/2017/06/29/vivitrol-methadone-opioids/ (last visited May 15, 2018).

were unsustainable and caused the Company to be subjected to heightened regulatory and legislative scrutiny.

58. Following the media reports about Alkermes' deceptive practices for selling Vivitrol, on July 27, 2017, the Company disclosed that it had received a subpoena from an Office of the U.S. Attorney on June 22, 2017, for documents related to Vivitrol.

59. According to the Company's most recent Form 10-Q filing, made on April 26, 2018, the Company continues to comply with the U.S. government concerning this subpoena.

60. On November 6, 2017, U.S. Senator Kamala Harris (D-CA) announced the opening of an investigation into Alkermes' sales practices for Vivitrol.

Defendants Misleadingly Claim that Vivitrol Users Will Not Relapse

61. Vivitrol does not contain any opioid ingredient. Instead, it is an extended-release formulation of naltrexone, which means that for the 28 days after receiving an injection of Vivitrol the patient's brain receptors for opioids will be blocked. However, Vivitrol does not provide a complete block during this 28-day time period – copious amounts of opioids can override Vivitrol's effect.

62. Vivitrol also does not prevent relapse during this 28-day time period, as users can still maintain a psychological addiction and desire for opioids even while taking Vivitrol. What Vivitrol does do, as explained in its FDA label, is offer the ***possibility*** of preventing relapse to opioid addiction. Vivitrol does not provide an ironclad guarantee against relapsing.

63. In addition, it is critical that patients receive Vivitrol shots every 28 days after their first shot, as it is necessary to maintain a constant flow of naltrexone in order for Vivitrol to continue to offer the possibility of not relapsing.

64. During the Class Period, Defendants misled investors regarding Vivitrol's efficacy during the 28 days following injection. Specifically, Defendants described Vivitrol as providing an absolute guarantee of no relapse, stating, for example, that "[i]f you take [Vivitrol] each month, you will not relapse to opioid dependence."

65. Defendants knew, or recklessly disregarded, that these statements were highly misleading. According to an article published by ProPublica, dated June 27, 2017 (the "6/27/17 Article"),[6] the author viewed PowerPoint slides from an in-house study regarding Vivitrol that was not publicly available at the time.

66. The PowerPoint slides referenced in the 6/27/17 Article discussing this in-house study, which was funded by Alkermes and included the participation of several doctors employed by Alkermes, were presented at ASAM's 45th Annual Medical-Scientific Conference held in Orlando, Florida, from April 10 to 13, 2014 (the "April 2014 ASAM Conference"). The April 2014 ASAM Conference was a non-public event. Members of the public could attend only if special access was granted. In the promotional materials for the April 2014 ASAM Conference, there was nothing that mentioned Alkermes or Vivitrol. This means that Alkermes' investors and analysts who follow the Company would not have known that important, non-public information about Vivitrol was being presented to the closed audience at this event.

67. At the April 2014 ASAM Conference, on Sunday, April 13, five papers were presented as part of a group session, including one entitled "The Extended-Release Naltrexone (XR-NTX) Opioid Dependence Registry: Clinical and Functional Effectiveness." Of the five doctors that were listed as being affiliated with this paper, four of them were, or had recently been, employed by Alkermes, including: (i) Bernard Silverman ("Silverman"), Alkermes' Vice President of Clinical

[6] Alec MacGillis, *The Last Shot*, ProPublica (June 27, 2017), https://www.propublica.org/article/vivitrol-opiate-crisis-and-criminal-justice (last visited May 15, 2018).

Strategy for Biostatistics; (ii) Jacqueline Zummo, Alkermes' Director of Medical Affairs; (iii) Asli Memisoglu, Alkermes' Senior Director of Biostatistics; and (iv) David Gastfriend, who was with the Treatment Research Institute at the time of the April 2014 ASAM Conference but had served as Alkermes' Vice President for Scientific Communications from 2004 until 2013.

68. According to the 6/27/17 Article, the PowerPoint slides of the in-house study presented at the April 2014 ASAM Conference found that nearly 30% of Vivitrol users never took their second shot of Vivitrol. This means that a significant number of Vivitrol patients relapsed within the 28-day time period that Defendants falsely claimed was a window where relapse would not happen.

69. Investors learned the truth about the limitations of Vivitrol's efficacy through the previously non-public information contained in the 6/27/17 Article.

70. Upon information and belief, following the Class Period, in March 2018, the results of the in-house study referenced in the PowerPoint slides at the April 2014 ASAM Conference were finally released to the public. Silverman is listed as one of the main authors of the study, which is entitled "Extended-release naltrexone (XR-NTX) for opioid use disorder in clinical practice: Vivitrol's Cost and Treatment Outcomes Registry." These results confirmed that the study took place from 2011 to 2013 across 32 treatment centers in the U.S., meaning that this study had concluded by the time of the April 2014 ASAM Conference.

71. Also in March 2018, another study on Vivitrol was formally released, which performed a retrospective case review of adverse events tracked by the FDA from October 2010 to March 2016 involving Vivitrol. Alkermes was required to provide this information to the FDA when the Company learns from medical providers or the criminal justice system of an overdose

suffered by someone who had been taking Vivitrol, meaning that Defendants knew, or recklessly disregarded, these adverse events by the start of the Class Period.

72. This study concluded that several deaths of Vivitrol patients occurred in the 28 days after the patient received a Vivitrol shot. Put another way, this study concluded that there are instances where Vivitrol patients were under the effect of naltrexone but nonetheless tried to override the block with a large dosage of opioids, which, tragically in these instances, led to their deaths.

73. Plaintiffs' counsel submitted a FOIA request to the FDA and received copies of adverse event reports that Alkermes submitted to the FDA before and during the Class Period. These documents confirm that Alkermes provided the FDA with instances where Vivitrol patients relapsed and fatally overdosed, meaning that Alkermes knew, or recklessly disregarded, the existence of these relapses in Vivitrol patients by the start of the Class Period.

74. Accordingly, Defendants knew, or recklessly disregarded, throughout the Class Period that Vivitrol did not guarantee against relapsing to opioid usage.

Defendants Misleadingly Claim that Vivitrol Is the Only Opioid Addiction Treatment that Can Lead to Abstinence

75. Before and during the Class Period, Defendants had no scientific basis for comparing the efficacy of Vivitrol to methadone or Suboxone because there had been no head-to-head studies comparing them. As a result, Defendants lacked a reasonable basis to represent to investors that Vivitrol provided any advantage over methadone or Suboxone.

76. Nonetheless, Defendants misleadingly claimed to investors during the Class Period that Vivitrol is "for those patients who want to live a drug-free life" and that only Vivitrol, not methadone or Suboxone, can guide addicts to abstinence. By speaking about these topics, investors assumed Defendants had some scientific basis, or at least a reasonable basis, for making these

statements. In reality, Defendants had no evidence to support these claims, and instead were making baseless statements designed to mislead investors about Vivitrol's potential.

77. Investors only learned that Defendants' statements comparing Vivitrol's efficacy to methadone and Suboxone were inaccurate and lacked a reasonable basis when two studies were published towards the end of the Class Period that showed Vivitrol was, at best, equivalent to methadone and Suboxone in achieving abstinence.

78. The first study was published on October 18, 2017, in *The Journal of the American Medical Association* (the "10/18/17 Study").[7] The 10/18/17 Study was the first-ever direct comparison of Vivitrol and Suboxone conducted in a controlled clinical setting. The 10/18/17 Study found that Vivitrol and Suboxone were equally effective at maintaining short-term abstinence from opioid usage. As a result, investors learned for the first time that Vivitrol was no better than Suboxone at achieving abstinence.

79. The second study was published during the trading day on November 14, 2017, the last day of the Class Period (the "11/14/17 Study").[8] The 11/14/17 Study, which was being undertaken at a similar time as the 10/18/17 Study, also compared the effectiveness of Vivitrol versus Suboxone and similarly concluded that they were equivalent.

80. However, the 11/14/17 Study also included an important caveat, which was that, given the need for Vivitrol patients to detox before beginning this treatment, more than 25% of those

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[7] Lars Tanum, Kristin Klemmetsby Solli & Zill-e-Huma Latif, *Effectiveness of Injectable Extended-Release Naltrexone vs Daily Buprenorphine-Naloxone for Opioid Dependence*, JAMA Psychiatry, https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2657484?redirect=true (last visited May 15, 2018).

[8] Dr. Joshua D. Lee, et al., *Comparative effectiveness of extended-release naltrexone versus buprenorphine-naloxone for opioid relapse prevention (X:BOT): a multicentre, open-label, randomised controlled trial*, The Lancet (Nov. 14, 2017) https://www.thelancet.com/journals/lancet/ article/PIIS0140-6736(17)32812-X/fulltext (last visited May 15, 2018).

patients assigned to the Vivitrol group in this study dropped out before they even took their first shot. As such, the 11/14/17 Study reinforced that Vivitrol is actually less effective than Suboxone at achieving abstinence.

81. Accordingly, the 10/18/17 Study and the 11/14/17 Study establish that Defendants lacked a reasonable basis for their positive Class Period statements regarding Vivitrol's efficacy as compared to methadone and Suboxone.

MATERIALLY FALSE AND MISLEADING STATEMENTS MADE DURING THE CLASS PERIOD

82. During the Class Period, Defendants disseminated materially false and misleading statements, and otherwise violated an obligation to disclose material information, concerning: (i) the marketing tactics used by Alkermes to exponentially increase Vivitrol sales; and (ii) Vivitrol's efficacy, both in terms of its ability to prevent relapse to opioid use and as compared to methadone and Suboxone.

Statements that Omitted Alkermes' Deceptive Vivitrol Sales Practices

83. The Class Period begins on February 24, 2015. On that day, Alkermes filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2014 (the "2014 Form 10-K"). The Individual Defendants signed the 2014 Form 10-K. With regard to the Company's marketing efforts for Vivitrol sales, the 2014 Form 10-K stated, in relevant part:

> We are responsible for the marketing of VIVITROL in the U.S. ***We focus our sales and marketing efforts on specialist physicians in private practice and in public treatment systems. We use customary pharmaceutical company practices to market our product*** and to educate physicians, such as sales representatives calling on individual physicians, advertisements, professional symposia, selling initiatives, public relations and other methods. We provide, or contract with third- party vendors to provide, customer service and other related programs for our product, such as product-specific websites, insurance research services and order, delivery and fulfillment services.

84. The statement that "[w]e use customary pharmaceutical company practices to market our product . . ." referenced in ¶83 was materially false and misleading because Defendants knew, or recklessly disregarded, that:

(a) Alkermes' growth through Vivitrol sales was not occurring organically, but was instead achieved through deceptive marketing campaigns to influence policymakers to use Vivitrol over other more affordable and efficacious treatment options;

(b) that these deceptive marketing campaigns centered on falsely claiming to non-medical professionals that Vivitrol was a better opioid addiction treatment compared to methadone and Suboxone, the established treatments, because it was non-addictive and had no street value, even though there was no scientific basis for such claims;

(c) the foregoing conduct, when disclosed, would foreseeably subject Alkermes to heightened regulatory and legislative scrutiny;

(d) accordingly, the Company's revenues derived from Vivitrol sales through these methods were unsustainable; and

(e) as a result of the foregoing, Alkermes shares traded at artificially inflated prices during the Class Period.

85. On September 17, 2015, the Company held a conference call for analysts and investors (the "9/17/15 Conf Call") to discuss Alkermes' performance, including Vivitrol sales and the Company's marketing efforts related thereto. During the 9/17/15 Conf Call, defendant Pops stated, in pertinent part, as follows:

> What's so gratifying, what's so exciting, though, is that now I think we have pilot programs in the criminal justice system in 29 states and almost 80 different programs. You've heard us talking about this for years, and these are slow gestation things, where we'll start in a community. ***It might be a single sheriff or it might be a single drug court, starts using VIVITROL and they start seeing outcomes and it begins to proliferate.*** All of a sudden funding starts to become an impediment, so

> they have to figure out how to appropriate new funds, either at the municipal level or the county level or the state level. Now they're starting to see governors signing bills that appropriate money for VIVITROL treatment programs. It happened in Ohio, Governor Kasich signed a bill; it happened in Illinois; it happened in Florida.

86. The statement that "[i]t might be a single sheriff or it might be a single drug court, starts using Vivitrol and they start seeing outcomes and it begins to proliferate" referenced above in ¶85 was materially false and misleading for the reasons set forth above in ¶84.

87. On January 12, 2016, the Company held a conference call for analysts and investors (the "1/12/16 Conf Call") to discuss Alkermes' performance, including Vivitrol sales and the Company's marketing efforts related thereto. During the 1/12/16 Conf Call, defendant Pops stated, in pertinent part, as follows:

> That's the 100 programs in 30 states that start very small. Sometimes these can be a single jail or a single sheriff using 30 cartons in a year and running their own experiment, and seeing these results and then lobbying to get more funding. And so, you can see it. ***It's just a very grassroots, viral thing that's propagating throughout the country*** because there's such an – it's difficult to overstate how different treatment with Vivitrol is in opioid dependence compared to treating somebody with Suboxone or methadone, where you maintain the patient's physical dependence on the opioid.

88. The statement that "[the adoption of Vivitrol by policymakers is] just a very grassroots, viral thing that's propagating throughout the country" referenced above in ¶87 was materially false and misleading for the reasons set forth above in ¶84.

89. On February 25, 2016, Alkermes filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2015 (the "2015 Form 10-K"). The Individual Defendants signed the 2015 Form 10-K. With regard to the Company's marketing efforts for Vivitrol sales, the 2015 Form 10-K stated, in relevant part:

> We are responsible for the marketing of VIVITROL and ARISTADA in the U.S. We focus our sales and marketing efforts on specialist physicians in private practice and in public treatment systems. ***We use customary pharmaceutical company practices to market our product*** and to educate physicians, such as sales representatives calling on individual physicians, advertisements, professional

> symposia, selling initiatives, public relations and other methods. We provide, or contract with third-party vendors to provide, customer service and other related programs for our products, such as product-specific websites, insurance research services and order, delivery and fulfillment services.

90. The statement that "[w]e use customary pharmaceutical company practices to market our product . . ." referenced above in ¶89 was materially false and misleading for the reasons set forth above in ¶84.

91. On February 25, 2016, the Company held a conference call for analysts and investors (the "2/25/16 Conf Call") to discuss Alkermes' performance, including Vivitrol sales and the Company's marketing efforts related thereto. During the 2/25/16 Conf Call, defendant Pops stated, in pertinent part, as follows:

> ***What's most exciting is how an expanding array of states, counties, and municipalities are beginning to integrate the use of Vivitrol into their criminal justice and healthcare systems***.

92. The statement referenced above in ¶91 was materially false and misleading for the reasons set forth above in ¶84.

93. On April 28, 2016, the Company held a conference call for analysts and investors (the "4/28/16 Conf Call") to discuss Alkermes' performance, including Vivitrol sales and the Company's marketing efforts related thereto. During the 4/28/16 Conf Call, defendant Pops stated, in pertinent part, as follows:

> What's so fascinating of course is the 10 years to be an overnight success with VIVITROL. We've been doing this stuff for six years now on the opioid side to lay the foundation for this. So we can do a lot, but what actually makes the plane take off the runway after lumbering down for a long time is the fact that, as [defendant Frates] mentioned in his remarks, ***it starts to become a little bit organic. That other jurisdictions see what is happening and they begin to start pushing for implementation of VIVITROL programs on their own without our help***.

94. The statements that "[increasing Vivitrol sales] starts to become a little bit organic" and "[t]hat other jurisdictions see what is happening and they begin to start pushing for

implementation of Vivitrol programs on their own without out help" referenced above in ¶93 were materially false and misleading for the reasons set forth above in ¶84.

95. On July 28, 2016, the Company held a conference call for analysts and investors (the "7/28/16 Conf Call") to discuss Alkermes' performance, including Vivitrol sales and the Company's marketing efforts related thereto. During the 7/28/16 Conf Call, defendant Frates stated, in pertinent part, as follows:

> In the quarter, VIVITROL net sales grew to $47.2 million, compared to $37.2 million for the same period last year. ***We're continuing to see accelerating sales growth in both commercial sales and even more so in Medicaid sales driven by our focus on criminal justice programs and our organic growth within the states***.

96. The statement that "[w]e're continuing to see accelerating sales growth . . . driven by our focus on criminal justice programs and our organic growth within the states" referenced above in ¶95 was materially false and misleading for the reasons set forth above in ¶84.

97. On November 8, 2016, the Company held a conference call for analysts and investors (the "11/8/16 Conf Call") to discuss Alkermes' performance, including Vivitrol sales and the Company's marketing efforts related thereto. During the 11/8/16 Conf Call, defendant Pops stated, in pertinent part, as follows:

> From very modest beginnings, now ***VIVITROL is becoming self-propagating***. There are more than 300 pilot programs or full programs now going on in 35 states around the country. And the figure shows the flavors of these, where -- from legislatures that have passed a new law that changes the way that funding and treatment is provided in the state, to public health initiatives that are happening outside the criminal justice system, just in kind of the Medicare and Medicaid world, to drug court initiatives and criminal justice reentry initiatives that are very VIVITROL focused, ***because it's the only medication that has no diversion or addictive potential. But what's cool is the way these are beginning to burgeon is because -- not Alkermes people out in those states necessarily pushing all these programs***. It's how internal references are starting to occur between judges and judges, and drug court professionals and drug court professionals, and police chiefs and police chiefs.

98. The statements that "Vivitrol is becoming self-propagating . . . because it's the only medication that has no diversion or addictive potential" and "the way these are beginning to burgeon

is because – not Alkermes people out in those states necessarily pushing all these programs" referenced above in ¶97 were materially false and misleading for the reasons set forth above in ¶84.

99. On February 17, 2017, Alkermes filed an Annual Report on Form 10-K with the SEC reporting the Company's financial and operating results for the year ended December 31, 2016 (the "2016 Form 10-K"). The Individual Defendants signed the 2016 Form 10-K.

100. With regard to the Company's marketing efforts for Vivitrol sales, the 2016 Form 10-K stated, in relevant part:

> We are responsible for the marketing of VIVITROL and ARISTADA in the U.S. We focus our sales and marketing efforts on specialist physicians in private practice and in public treatment systems. ***We use customary pharmaceutical company practices to market our product*** and to educate physicians, such as sales representatives calling on individual physicians, advertisements, professional symposia, selling initiatives and other methods. We provide, or contract with third-party vendors to provide, customer service and other related programs for our products, such as product-specific websites, insurance research services and order, delivery and fulfillment services.

101. The statement that "[w]e use customary pharmaceutical company practices to market our product . . ." referenced above in ¶100 was materially false and misleading for the reasons set forth above in ¶84.

False Statements Concerning Vivitrol's Efficacy

102. Separate from Defendants' false and misleading statements concerning Alkermes' marketing efforts for Vivitrol sales, Defendants repeatedly misled investors during the Class Period by portraying Vivitrol as always preventing relapse to opioid usage during the 28 days after users received the shot, even though Defendants knew, or recklessly disregarded, that many users relapse during this time period. For example, on November 18, 2015, the Company held a conference call for analysts and investors (the "11/18/15 Conf Call") to discuss, among other things, Vivitrol. During the 11/18/15 Conf Call, defendant Pops stated, in pertinent part, as follows:

> ***This is a once-a-month medication that blocks opioid receptors in the brain and prevents relapse to opioid dependence***.

103. The statement referenced in ¶102 was materially false and misleading because defendant Pops knew, or recklessly disregarded, that:

(a) Vivitrol only offers the ***potential*** for not relapsing in the 28 days after the shot is administered, but does not guarantee relapse prevention during this time period;

(b) defendant Pops knew this because an internal, nonpublic study conducted by Alkermes doctors before the Class Period showed that approximately 30 percent of Vivitrol users relapsed to opioid use before a second shot was administered, *i.e.*, during the period of time that Vivitrol is supposed to absolutely prevent relapse;

(c) the foregoing information would foreseeably cause current and potential Vivitrol customers to reconsider purchasing Vivitrol; and

(d) as a result of the foregoing, Alkermes shares traded at artificially inflated prices during the Class Period.

104. Defendants also repeatedly misled investors during the Class Period by portraying Vivitrol as being the only method through which addicts could return to a drug-free life, even though Defendants knew, or recklessly disregarded, that the Company had no scientific data to support their view that Vivitrol was more effective at accomplishing this than the established treatments of methadone and Suboxone. For example, during the 1/12/16 Conf Call, defendant Pops stated, in pertinent part, as follows:

> So, [Vivitrol] is for that group of patients who don't want to be addicted to opioid anymore, don't want to be drug users. So, it's not all patients, but ***it's for those patients who want to live a drug-free life***.

105. The statement that "[Vivitrol is] for those patients who want to live a drug-free life" referenced above in ¶104 was materially false and misleading because defendant Pops knew, or recklessly disregarded, that:

(a) methadone and Suboxone also enable patients to live a drug-free life;

(b) not a single study had been completed comparing Vivitrol's efficacy to methadone or Suboxone;

(c) the foregoing information would foreseeably cause current and potential Vivitrol customers to reconsider purchasing Vivitrol; and

(d) as a result of the foregoing, Alkermes shares traded at artificially inflated prices during the Class Period.

106. During the 1/12/16 Conf Call, defendant Pops further stated, in pertinent part, as follows:

> Vivitrol is -- you live a drug-free life. You have to be detoxified, so you have to go through the process of detoxification. That can happen brutally in a jail cell, or it can happen more gently under medical supervision. ***Then you get that monthly injection and you cannot reestablish physical dependence on the opioid***.

107. The statement that "[t]hen you get that monthly injection and you cannot reestablish physical dependence on the opioid" referenced above in ¶106 was materially false and misleading for the reasons set forth above in ¶103.

108. In addition, during the 1/12/16 Conf Call, defendant Pops stated, in pertinent part, as follows:

> That's the 100 programs in 30 states that start very small. Sometimes these can be a single jail or a single sheriff using 30 cartons in a year and running their own experiment, and seeing these results and then lobbying to get more funding. And so, you can see it. It's just a very grassroots, viral thing that's propagating throughout the country because there's such an – ***it's difficult to overstate how different treatment with Vivitrol is in opioid dependence compared to treating somebody with Suboxone or methadone, where you maintain the patient's physical dependence on the opioid.***

109. The statement that "it's difficult to overstate how different treatment with Vivitrol is in opioid dependence compared to treating somebody with Suboxone or methadone, where you maintain the patient's physical dependence on the opioid" referenced above in ¶108 was materially false and misleading for the reasons set forth above in ¶105.

110. On March 8, 2016, the Company held a conference call for analysts and investors (the "3/8/16 Conf Call") to discuss, among other things, Vivitrol. During the 3/8/16 Conf Call, defendant Frates stated, in pertinent part, as follows:

> So, we have someone addicted to opiates, and we move them and transition them onto a different opiate. And we keep them addicted, but in a safer, more controlled way, under the care of a physician. No doubt that's an important step forward. ***But the idea of actually moving those patients and giving them an opportunity to get to a drug-free life, to get to abstinence – that's what our drug does***.

111. The statement that "giving [patients] an opportunity to get to a drug-free life, to get to abstinence – that's what our drug does" referenced above in ¶110 was materially false and misleading because defendant Frates knew, or recklessly disregarded, that:

(a) methadone and Suboxone also enable patients to live a drug-free life;

(b) not a single study had been completed comparing Vivitrol's efficacy to methadone or Suboxone;

(c) the foregoing information would foreseeably cause current and potential Vivitrol customers to reconsider purchasing Vivitrol; and

(d) as a result of the foregoing, Alkermes shares traded at artificially inflated prices during the Class Period.

112. During the 3/8/16 Conf Call, defendant Frates further stated, in pertinent part, as follows:

> You have to be detoxed. So, you have to go through 7 to 10 days of detox to be opiate-free. ***And then you take an injection of Vivitrol, and that prevents your***

> ***relapse, according to our label, back to opiate dependence, because it's an antagonist and it stays on board for a month***.

113. The statement that "[a]nd then you take an injection of Vivitrol, and that prevents your relapse, according to our label, back to opiate dependence, because it's an antagonist and it stays on board for a month" referenced above in ¶112 was materially false and misleading because defendant Frates knew, or recklessly disregarded, that:

(a) Vivitrol only offers the ***potential*** for not relapsing in the 28 days after the shot is administered, but does not guarantee relapse prevention during this time period;

(b) defendant Pops knew this because an internal, nonpublic study conducted by Alkermes doctors before the Class Period showed that approximately 30 percent of Vivitrol users relapsed to opioid use before a second shot was administered, *i.e.*, during the period of time that Vivitrol is supposed to absolutely prevent relapse;

(c) the foregoing information would foreseeably cause current and potential Vivitrol customers to reconsider purchasing Vivitrol; and

(d) as a result of the foregoing, Alkermes shares traded at artificially inflated prices during the Class Period.

114. On November 16, 2016, the Company held a conference call for analysts and investors (the "11/16/16 Conf Call") to discuss, among other things, Vivitrol. During the 11/16/16 Conf Call, defendant Pops stated, in pertinent part, as follows:

> You see the cover of the Washington Post Magazine. Breaking good: VIVITROL, a drug given as a monthly shot is helping addicts stay clean. This is the preferred drug in the criminal justice system because it has no addictive potential. It is given once a month. Think about in the context of parole or probation. ***You know that person gets their shot once a month. They are not going to relapse to opioid dependence***. New York magazine, Forbes magazine, CBS, NPR, AP, Fox News, it's all happening now. People are beginning to -- this is moving itself into the public consciousness.

115. The statement that "[y]ou know that person gets their shot once a month. They are not going to relapse to opioid dependence " referenced above in ¶114 was materially false and misleading for the reasons set forth above in ¶103.

116. On March 7, 2017, the Company held a conference call for analysts and investors (the "3/7/17 Conf Call") to discuss, among other things, Vivitrol. During the 3/7/17 Conf Call, defendant Pops stated, in pertinent part, as follows:

> Vivitrol. So, Vivitrol also is a unique medicine. And starting on the far left, the indication, it is the only drug -- the FDA label says it is approved, indicated for preventing relapse to opioid dependence. That's a remarkable statement for a clinician and for a patient. ***If you take this medicine each month, you will not relapse to opioid dependence***.

117. The statement "[i]f you take this medicine each month, you will not relapse to opioid dependence" referenced above in ¶116 was materially false and misleading for the reasons set forth above in ¶103.

118. On June 6, 2017, the Company held a conference call for analysts and investors (the "6/6/17 Conf Call") to discuss, among other things, Vivitrol. During the 6/6/17 Conf Call, defendant Frates stated, in pertinent part, as follows:

> So now on to VIVITROL. Gaining more and more recognition. This is a monthly injection, a 28-day injection of naltrexone, extended-release naltrexone for the treatment of opioid and alcohol dependence. It really stands alone as the only nonaddictive product in the market. Naltrexone is an antagonist. It has no street value. It's never been diverted. And ***with 28 days of relapse prevention, as the label says, it prevents relapse to opioid dependence***.

119. The statement "with 28 days of relapse prevention, as the label says, it prevents relapse to opioid dependence" referenced above in ¶118 was materially false and misleading for the reasons set forth above in ¶113.

Investors Belatedly Learn About Alkermes' Deceptive Practices and Vivitrol's Limitations

120. On Sunday, June 11, 2017, the 6/11/17 Article was published and described Alkermes' aggressive efforts to market Vivitrol by disparaging the efficacy of other addiction treatments, stating, in part:

> Five years ago, Vivitrol was a treatment for opioid addiction that was struggling to find a market. Now, its sales and profile are rising fast, thanks to its manufacturers' shrewd use of political connections, and ***despite scant science to prove the drug's efficacy.***
>
> * * *
>
> The company's strategy highlights the profit opportunities that drug companies and investors see in an opioid epidemic that killed 91 Americans every day in 2015 and is growing worse. But ***some of its marketing tactics***, and Mr. Price's comments, ***ignore widely accepted science***, as nearly 700 experts in the field wrote the health secretary in a letter.
>
> ***Not a single study has been completed comparing Vivitrol with its less expensive competitors.***
>
> * * *
>
> Alkermes executives say they welcome any addiction treatment. ***But in pitches to investors, doctors, law enforcement officials and legislators, they have presented Vivitrol as something of a miracle drug, a cleaner alternative to Suboxone, the most common formulation of buprenorphine. They described Suboxone as an addictive "black market" or "street" drug, emphasizing that it is smuggled into prison***.
>
> That view has resonated with drug court judges and sheriffs. But some addiction and public health specialists complain that the company unfairly denigrates its competition, ***without any data to suggest Vivitrol has better outcomes***.
>
> "If you care about actually solving the problem, you cannot stigmatize the most effective treatments," said Dr. Joshua Sharfstein, a former Maryland health secretary who is now an associate dean at the Johns Hopkins Bloomberg School of Public Health. "This is a company that has put its own perverted idea of market success ahead of actually solving the problem."
>
> ***As health secretary, he said, he had to call a meeting to tell Alkermes to "back off talking down methadone and buprenorphine" to legislators as the company aggressively lobbied to get Maryland to use Vivitrol***.

> "They're exploiting a stigma that exists out of a very narrow view of their own economic self-interest," he said. "And the result is going to be more people dying if they cannot get access to effective treatment."
>
> * * *
>
> ***But for all the company's assertions that Vivitrol is superior to Suboxone or methadone, it offers no data***. Dr. Nora Volkow, director of the National Institute on Drug Abuse, said she and other experts were eagerly awaiting results from the first study comparing outcomes of treatment with Vivitrol and Suboxone, expected this fall.

121. The next morning, on June 12, 2017, the 6/12/17 Article was published. This article discussed the Company's unethical lobbying tactics to push for state legislatures to enact laws making it more difficult to obtain methadone or buprenorphine. The 6/12/17 Article stated, in pertinent part, that:

> But a number of people working in the field of addiction policy are concerned about [Alkermes'] tactics [for selling Vivitrol].
>
> "***In a number of states, there has been a significant push by Alkermes and their lobbyists to really squelch other treatment[s], so that they can get access to bigger markets for their drug***," says Dr. Corey Waller, an addiction specialist who heads legislative advocacy for the American Society of Addiction Medicine.
>
> Waller says people should be wary of the notion that Vivitrol is better than other drugs to treat opioid addiction. ***No studies comparing Vivitrol with buprenorphine or methadone have been published.***
>
> [Dr. Andy] Chambers [, an addiction psychiatrist in Indianapolis,] expressed similar concerns. He says Alkermes operates as though methadone and buprenorphine are competitors, when the drugs are actually meant for different types of patients. "That's really an unfortunate dynamic," he says. "They're not designed to do the same things. It's like comparing apples and oranges."
>
> * * *
>
> Leading up to the passage of the Comprehensive Addiction and Recovery Act in 2016, the company sought increased federal regulation of buprenorphine. "***This is one of the most intense behind-the-scenes lobbying efforts,***" said a Democratic congressional staffer, who was not authorized to speak on the record. "It frustrated me to no end for 2 1/2, three years."
>
> ***[Alkermes] circulated a document***, obtained by NPR and Side Effects, ***that presented slanted material about buprenorphine, focused on the drug's potential***

> ***for diversion and abuse while largely ignoring its benefits for individuals and for public health. "This is basically a very long attempt to bash buprenorphine***," said [Basia] Andraka-Christou [,a researcher at the Fairbanks School of Public Health in Indianapolis,] when we showed her the documents.
>
> ***A spokesperson for Alkermes, Matthew Henson, acknowledged in a phone interview that the company circulated the white paper, which he described as a "working document" meant to educate federal lawmakers about medication-assisted treatment options. The document doesn't mention Vivitrol. Asked why Alkermes was circulating a document focused on a medication it doesn't manufacture, Henson said he would get back to us. He never did***.
>
> As lawmakers sought to expand access to treatment, the white paper called for stricter regulation of buprenorphine through a bill dubbed the Opioid Addiction Treatment Modernization Act, introduced in the House in June 2015. ***"The legislation they wanted introduced was actually going the other direction, in terms of making it more onerous to be a doctor wanting to prescribe these medications, and would have hurt treatment capacity in this country,"*** says the staffer.

122. The next day, on June 13, 2017, *The Fix*, an online addiction and recovery website, published an article that was also critical of Vivitrol (the "6/13/17 Article").[9] The 6/13/17 Article described how Alkermes was "***pushing hard to smother treatment options like Suboxone and methadone to make way for Vivitrol's rise***."

123. Then, the 6/27/17 Article was published, disclosing, among other things, that:

> ***More disconcerting were the results of an in-house study by Alkermes, which it has not yet published. I viewed a PowerPoint presentation from the company, based on that study, which indicated that nearly 30 percent of the people being tracked dropped out before the second shot***, another third dropped out by the third month, and fewer than 20 percent made it a full year.

124. Following this significant negative press coverage on Vivitrol, on July 27, 2017, the Company disclosed that, on June 22, 2017, it had received a subpoena from an Office of the U.S. Attorney for documents related to Vivitrol.

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[9] Kelly Burch, *Maker of Vivitrol Lobbies To Influence Legislation on Medication-Assisted Treatment*, The Fix (June 13, 2017), https://www.thefix.com/maker-vivitrol-lobbies-influence-legislation-medication-assisted-treatment (last visited May 15, 2018).

125. Then, the 10/18/17 Study was published on October 18, 2017, revealing that the first scientific test comparing Vivitrol to Suboxone that Vivitrol was only equally as effective at treating opioid dependence.

126. Thereafter, on November 6, 2017, U.S. Senator Kamala Harris announced the opening of an investigation into Alkermes' sales practices for Vivitrol. Senator Harris specifically stated that the Company "pursued an aggressive lobbying and marketing campaign" for its medication, convincing judges and prison officials to use it rather than more proven addiction-treatment products, and spent hundreds of thousands of dollars lobbying policymakers.

127. Finally, during the trading day on November 14, 2017, the 11/14/17 Study was published, which demonstrated that not only was Vivitrol equally as effective as Suboxone, but that it is actually less effective given the need for patients to detox before receiving Vivitrol.

128. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's common stock, Plaintiff and other Class members have suffered significant losses and damages.

ADDITIONAL SCIENTER ALLEGATIONS

129. Several factors support a strong inference of the Individual Defendants' scienter during the Class Period in addition to those described in ¶¶23-81 above, including: (i) insider stock sales; (ii) the misstatements and omissions of material facts concern the Company's core operations, about which the Individual Defendants were repeatedly questioned and spoke; and (iii) corporate scienter.

Insider Stock Sales

130. Defendants were motivated to engage in their fraudulent course of conduct in order to allow high-level Alkermes officers and directors, including the Individual Defendants, to sell shares

of their personally-held Alkermes common stock at artificially inflated prices, which yielded them gross proceeds of ***over $103 million*** during the Class Period, as follows:

Name	Title	Date	No. of Shares Sold	Price	Proceeds
Biberstein, Kathryn L.	Officer	01-Dec-2016	7,067	56.63	$400,204
		01-Dec-2016	7,933	55.69	$441,789
		06-Dec-2016	5,000	56.24	$281,200
		07-Dec-2016	4,100	56.50	$231,650
		07-Dec-2016	900	57.11	$51,399
		08-Dec-2016	4,145	55.42	$229,716
		03-Apr-2017	3,763	58.35	$219,571
		03-Apr-2017	300	59.13	$17,739
		03-Apr-2017	10,937	57.41	$627,893
		11-Sep-2017	11,067	51.18	$566,409
		11-Sep-2017	2,499	51.77	$129,373
			57,711		**$3,196,943**
Breyer, Robert A.	Director	01-Apr-2015	5,000	61.22	$306,100
		04-May-2015	2,000	60.00	$120,000
		01-Jun-2015	2,000	60.78	$121,560
		01-Jul-2015	2,000	64.90	$129,800
		03-Aug-2015	2,000	69.61	$139,220
		01-Sep-2015	2,000	61.43	$122,860
		01-Oct-2015	516	60.00	$30,960
		02-Oct-2015	1,484	60.00	$89,040
		02-Nov-2015	2,000	71.80	$143,600
		01-Dec-2015	2,000	73.46	$146,920
		04-Jan-2016	2,000	77.33	$154,660
		10-Nov-2016	20,000	60.00	$1,200,000
		04-Jan-2017	4,000	60.00	$240,000
		02-Mar-2017	4,000	60.00	$240,000
			51,000		**$3,184,720**
Brown, Iain Michael	Officer	29-Oct-2015	10,822	69.99	$757,432
		18-Apr-2016	5,368	39.27	$210,801
		06-Sep-2016	3,469	46.36	$160,823
		06-Sep-2016	26,507	45.87	$1,215,876
			46,166		**$2,344,932**
Cooke, Shane M.	President	23-Mar-2015	4,700	65.87	$309,589
		23-Mar-2015	13,300	65.14	$866,362
		23-Apr-2015	18,000	62.55	$1,125,900
		26-May-2015	17,300	60.29	$1,043,017
		26-May-2015	700	60.81	$42,567
		23-Jun-2015	17,100	66.80	$1,142,280
		23-Jun-2015	900	67.56	$60,804
		23-Jul-2015	2,401	70.40	$169,030

		23-Jul-2015	15,599	69.70	$1,087,250
		24-Aug-2015	1,000	53.40	$53,400
		24-Aug-2015	1,200	54.65	$65,580
		24-Aug-2015	5,661	57.78	$327,093
		24-Aug-2015	5,107	58.64	$299,474
		24-Aug-2015	2,500	56.67	$141,675
		24-Aug-2015	2,532	59.41	$150,426
		23-Sep-2015	13,900	67.29	$935,331
		23-Sep-2015	4,100	66.41	$272,281
		23-Oct-2015	7,926	61.59	$488,162
		23-Oct-2015	10,074	62.38	$628,416
		23-Nov-2015	17,100	72.59	$1,241,289
		23-Nov-2015	900	73.07	$65,763
		23-Dec-2015	8,500	76.73	$652,205
		23-Dec-2015	9,500	77.67	$737,865
		04-Jan-2017	2,543	60.01	$152,605
		05-Jan-2017	300	60.10	$18,030
		06-Jan-2017	6,607	60.07	$396,882
		09-Jan-2017	550	60.27	$33,149
		02-Mar-2017	20,000	60.00	$1,200,000
		20-Mar-2017	300	60.00	$18,000
		21-Mar-2017	1,600	60.10	$96,160
		23-Mar-2017	6,030	60.01	$361,860
		29-Mar-2017	2,070	60.00	$124,200
		01-May-2017	3,500	60.05	$210,175
		04-May-2017	6,500	60.05	$390,325
		08-Jun-2017	10,000	60.33	$603,300
			240,000		**$15,510,447**
Ehrich, Elliot W.	Officer	16-Mar-2015	18,000	66.81	$1,202,580
		21-Apr-2015	10,228	61.99	$634,034
		21-Apr-2015	14,772	62.66	$925,614
		13-Apr-2016	500	38.44	$19,220
		13-Apr-2016	11,198	37.63	$421,381
		26-Jul-2016	800	51.82	$41,456
		27-Jul-2016	34,399	51.95	$1,787,028
		06-Sep-2016	7,500	45.93	$344,475
		06-Sep-2016	2,500	46.31	$115,775
		16-Sep-2016	5,000	48.87	$244,350
		21-Sep-2016	1,166	50.81	$59,244
		22-Sep-2016	3,834	50.84	$194,921
		12-Dec-2016	16,983	55.15	$936,612
		15-Dec-2016	5,000	55.99	$279,950
		04-Jan-2017	2,500	60.01	$150,025
		04-Jan-2017	5,000	58.83	$294,150
		05-Jan-2017	400	60.08	$24,032
		06-Jan-2017	2,100	60.12	$126,252
		17-Jan-2017	11,983	54.32	$650,917

		15-Feb-2017	1,000	58.17	$58,170
		16-Feb-2017	3,915	56.05	$219,436
		16-Feb-2017	6,085	56.84	$345,871
		15-Mar-2017	6,900	57.00	$393,300
		15-Mar-2017	4,100	56.29	$230,789
		17-Apr-2017	10,000	56.60	$566,000
			185,863		**$10,265,581**
Defendant Frates, James M.	Chief Financial Officer	10-Mar-2015	8,600	66.15	$568,890
		10-Mar-2015	1,400	66.87	$93,618
		15-Apr-2015	10,000	62.42	$624,200
		12-May-2015	10,000	59.34	$593,400
		16-Jun-2015	10,000	58.63	$586,300
		14-Jul-2015	8,485	66.37	$563,149
		14-Jul-2015	11,515	65.37	$752,736
		11-Aug-2015	6,926	68.13	$471,868
		11-Aug-2015	3,074	67.63	$207,895
		15-Sep-2015	10,800	70.85	$765,180
		15-Sep-2015	9,200	71.39	$656,788
		13-Oct-2015	4,346	60.72	$263,889
		13-Oct-2015	5,949	60.20	$358,130
		13-Oct-2015	9,705	59.09	$573,468
		10-Nov-2015	10,000	72.34	$723,400
		07-Dec-2016	856	57.22	$48,980
		07-Dec-2016	5,496	55.65	$305,852
		07-Dec-2016	17,379	56.44	$980,871
		14-Dec-2016	24,900	54.72	$1,362,528
		14-Dec-2016	100	55.20	$5,520
		07-Mar-2017	24,600	59.07	$1,453,122
		07-Mar-2017	400	59.57	$23,828
		08-Nov-2017	20,932	47.58	$995,945
			214,663		**$12,979,557**
Gaffin, David Joseph	Officer	06-Sep-2016	2,382	45.92	$109,381
		03-Jan-2017	2,500	55.40	$138,500
			4,882		**$247,881**
Landine, Michael J.	Officer	10-Sep-2015	4,300	68.06	$292,658
		10-Sep-2015	5,700	67.26	$383,382
		17-Sep-2015	6,206	70.92	$440,130
		17-Sep-2015	3,794	71.65	$271,840
		01-Dec-2015	302	73.55	$22,212
		01-Dec-2015	1,400	73.11	$102,354
		01-Dec-2015	8,298	71.97	$597,207
		07-Dec-2015	1,000	73.71	$73,710
		07-Dec-2015	2,750	72.77	$200,118
		20-Apr-2016	9,993	40.97	$409,413
		20-Apr-2016	6,882	41.26	$283,951

		09-Nov-2016	2,870	56.89	$163,274
		09-Nov-2016	2,000	55.19	$110,380
		09-Nov-2016	5,130	56.24	$288,511
		16-Nov-2016	9,600	58.57	$562,272
		16-Nov-2016	400	59.12	$23,648
		30-Nov-2016	1,500	58.51	$87,765
		30-Nov-2016	8,500	57.33	$487,305
		11-May-2017	10,000	57.01	$570,100
		18-May-2017	1,300	57.81	$75,153
		18-May-2017	8,700	57.14	$497,118
		01-Nov-2017	15,000	48.71	$730,650
			115,625		**$6,673,151**
Mitchell, Paul J.	Director	15-Apr-2015	1,500	62.71	$94,065
		01-May-2015	1,500	55.79	$83,685
		01-Jun-2015	1,500	60.78	$91,170
		17-Jun-2015	15,500	65.10	$1,009,050
		04-Jan-2016	2,000	77.33	$154,660
		04-Feb-2016	2,000	32.81	$65,620
		04-Mar-2016	2,000	32.80	$65,600
		04-Apr-2016	2,000	35.65	$71,300
		04-May-2016	2,000	38.60	$77,200
		06-Jun-2016	2,000	44.98	$89,960
		05-Jul-2016	2,000	45.81	$91,620
		04-Aug-2016	2,000	49.48	$98,960
		06-Sep-2016	400	46.28	$18,512
		06-Sep-2016	1,600	45.83	$73,328
		04-Oct-2016	2,000	47.42	$94,840
		03-Jan-2017	1,500	55.40	$83,100
		01-Feb-2017	1,500	54.45	$81,675
		01-Mar-2017	1,500	57.06	$85,590
		03-Apr-2017	1,500	58.31	$87,465
		01-May-2017	1,500	58.74	$88,110
		01-Jun-2017	1,500	57.49	$86,235
		03-Jul-2017	1,500	58.11	$87,165
		01-Aug-2017	1,500	54.91	$82,365
		01-Sep-2017	1,500	50.77	$76,155
		02-Oct-2017	1,500	50.64	$75,960
		01-Nov-2017	1,000	49.16	$49,160
			56,000		**$3,062,550**
Peterson, Rebecca J.	Officer	03-Mar-2015	14,600	71.27	$1,040,542
		03-Mar-2015	775	72.04	$55,831
		05-Mar-2015	2,362	71.80	$169,592
		20-May-2015	1,050	62.50	$65,625
		20-May-2015	7,700	61.84	$476,168
		21-May-2015	16,150	61.53	$993,710
		21-May-2015	2,600	62.43	$162,318

		22-May-2015	1,058	61.11	$64,654
		26-May-2015	1,322	60.49	$79,968
		28-May-2015	200	60.71	$12,142
		28-May-2015	19,800	59.97	$1,187,406
		01-Jun-2015	1,983	60.78	$120,527
			69,600		**$4,428,482**
Defendant Pops, Richard F.	Chief Executive Officer	17-Sep-2015	27,579	71.58	$1,974,105
		17-Sep-2015	22,421	70.88	$1,589,200
		01-Dec-2015	23,748	71.99	$1,709,619
		01-Dec-2015	2,200	73.46	$161,612
		01-Dec-2015	24,052	72.48	$1,743,289
		07-Dec-2015	9,210	72.51	$667,817
		07-Dec-2015	882	73.52	$64,845
		07-Dec-2015	27,408	71.87	$1,969,813
		15-Mar-2016	25,000	31.40	$785,000
		22-Mar-2016	10,000	31.36	$313,600
		22-Mar-2016	15,000	32.05	$480,750
		12-Apr-2016	1,700	38.24	$65,008
		12-Apr-2016	23,300	37.76	$879,808
		19-Apr-2016	18,750	40.15	$752,813
		08-Nov-2016	21,054	53.05	$1,116,915
		08-Nov-2016	8,946	53.82	$481,474
		15-Nov-2016	27,940	58.78	$1,642,313
		15-Nov-2016	2,060	59.29	$122,137
		22-Nov-2016	23,115	58.43	$1,350,609
		22-Nov-2016	6,885	59.44	$409,244
		29-Nov-2016	27,950	56.93	$1,591,194
		29-Nov-2016	2,050	57.72	$118,326
		10-May-2017	7,841	57.67	$452,190
		10-May-2017	17,159	57.12	$980,122
		17-May-2017	32,406	58.37	$1,891,538
		17-May-2017	11,655	57.23	$667,016
		17-May-2017	5,939	59.06	$350,757
		24-May-2017	25,000	57.42	$1,435,500
		02-Nov-2017	50,000	48.87	$2,443,500
			501,250		**$28,210,114**
Pugh, Gordon G.	Officer	02-Mar-2015	6,800	71.72	$487,696
		02-Mar-2015	8,200	71.12	$583,184
		15-Apr-2015	13,750	63.21	$869,138
		19-May-2015	250	63.00	$15,750
		16-Jun-2015	32,977	63.11	$2,081,178
		01-Jul-2015	13,750	65.13	$895,538
		20-Jul-2015	18,750	70.10	$1,314,375
		03-Aug-2015	12,640	70.10	$886,064
		03-Aug-2015	810	69.53	$56,319
		03-Aug-2015	300	70.73	$21,219

		15-Dec-2016	16,690	57.62	$961,678
		16-Dec-2016	4,768	57.73	$275,257
			129,685		**$8,447,395**
Stejbach, Mark	Officer	02-Nov-2015	15,670	72.00	$1,128,240
		02-Nov-2015	2,330	72.51	$168,948
		01-Dec-2015	500	73.58	$36,790
		01-Dec-2015	15,200	71.99	$1,094,248
		01-Dec-2015	2,300	73.09	$168,107
		28-Dec-2015	10,000	80.24	$802,400
		04-Jan-2017	2,500	60.01	$150,025
		05-Jan-2017	300	60.09	$18,027
		06-Jan-2017	6,653	60.07	$399,646
		09-Jan-2017	547	60.27	$32,968
		08-Jun-2017	10,000	60.34	$603,400
			66,000		**$4,602,799**
TOTAL			**1,738,445**		**$103,154,552**

131. Indeed, the shares sold by Alkermes' officers and directors during the Class Period were highly unusual in both amount (based on the sheer dollar value of shares sold) and timing (made during a time period where Vivitrol sales suddenly began spiking due to Defendants' deceptive marketing campaign, as explained in ¶¶43-60 above).

132. Including vested shares that were technically available to be sold, during the Class Period defendant Pops sold 12.2% of his Alkermes holdings for proceeds totaling $28,210,114, of which $15,881,295, or 56.3%, were net profits.

133. Likewise, including vested shares that were technically available to be sold, during the Class Period defendant Frates sold 26.1% of his Alkermes holdings for proceeds totaling $12,979,557, of which $8,251,808, or 63.6%, were net profits.

134. Notably, neither Individual Defendant made a single open market purchase of Alkermes' common stock during the Class Period. In addition, every sale made by the Individual Defendants during the Class Period was from vested options or grants and did not represent resales of open market purchases of Alkermes common stock.

135. Further, that both Individual Defendants, along with numerous other senior Alkermes executives and directors, sold large portions of their Alkermes holdings during the Class Period for unusually large profits and at similar times supports a strong inference of scienter.

136. Accordingly, Defendants were motivated to make materially false and misleading statements and conceal material adverse information from investors so that they could personally profit from the artificial inflation in the trading price of Alkermes common stock resulting from their false and misleading statements and omissions during the Class Period.

Core Operations

137. The fraud alleged herein relates to the core business and operations of Alkermes so knowledge of the fraud may be imputed to Defendants. As explained in ¶¶30-42, nothing was more important to Alkermes during the Class Period than Vivitrol sales. Accordingly, it is appropriate to presume that Defendants were apprised of, had access to, or had actual knowledge of all material information related to Vivitrol during the Class Period, including the material information that was improperly withheld and/or misrepresented to investors.

138. Further, by virtue of their receipt of information reflecting the true facts regarding Alkermes' operations and its marketplace, as well as their control over and/or receipt of the Company's materially misleading misstatements and/or their associations with the Company that made them privy to confidential proprietary information concerning Alkermes, the Individual Defendants were active and culpable participants in the fraudulent scheme alleged herein. The Individual Defendants knew of and/or recklessly disregarded the falsity and misleading nature of the information, which they caused to be disseminated to the investing public. The fraud as described herein could not have been perpetrated without the knowledge and/or recklessness and complicity of personnel at the highest level of the Company, including the Individual Defendants.

Corporate Scienter

139. The allegations above also establish a strong inference that Alkermes as an entity acted with corporate scienter throughout the Class Period, as its officers, management, and agents, including, but not limited to, the Individual Defendants and the three Alkermes executives who presented at the April 2014 ASAM Conference, had actual knowledge of the misrepresentations and omissions of material facts set forth herein (for which they had a duty to disclose), or acted with reckless disregard for the truth because they failed to ascertain and to disclose such facts, even though such facts were available to them. Such material misrepresentations and/or omissions were done knowingly or with recklessness, and without a reasonable basis, for the purpose and effect of concealing Alkermes' true operating condition and present and expected financial performance from the investing public. By concealing these material facts from investors, Alkermes maintained and/or increased its artificially inflated common stock prices throughout the Class Period.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

140. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Alkermes common stock during the Class Period (the "Class"), and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

141. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Alkermes common stock was actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or

thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Alkermes or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

142. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

143. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

144. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Alkermes;
- whether the Individual Defendants caused Alkermes to issue false and misleading statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading statements;
- whether the price of Alkermes' common stock during the Class Period was artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, the proper measure of damages.

145. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET DOCTRINE

146. During the Class Period, the market for Alkermes common stock was an efficient market for the follow reasons, among others:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Alkermes common stock traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company's stock traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's common stock; and
- Plaintiff and members of the Class purchased or acquired Alkermes common stock between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

147. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

148. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United*

States, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

LOSS CAUSATION

149. As detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Alkermes common stock and operated as a fraud or deceit on purchasers of such stock by failing to disclose and misrepresenting adverse facts. As such misrepresentations and fraudulent conduct were disclosed and became apparent to the market, the price of Alkermes stock declined significantly as the prior artificial inflation came out of the Company's stock price.

150. As a result of their purchases of Alkermes common stock during the Class Period, Plaintiff and other Class members suffered economic loss, *i.e.*, damages, under the federal securities laws. Defendants' false and misleading statements had the intended effect and caused Alkermes common stock to trade at artificially inflated levels throughout the Class Period, reaching as high as $80.69 on December 28, 2015.

151. On Sunday, June 11, 2017, the 6/11/17 Article was published, exposing the deceptive marketing campaign and aggressive lobbying efforts Defendants had engaged in. The next day, the 6/12/17 Article was published, describing how Defendants misleadingly marketed Vivitrol, while simultaneously lobbying to restrict access to other opioid treatment programs.

152. The market reacted sharply to these reports, with shares of Alkermes stock declining from a close of $61.66 per share on Friday, June 9, 2017, to a low of $58.65 on Monday, June 12, 2017 – a decline of 4.9%. This drop removed inflation from the price of Alkermes' stock, causing real economic loss to investors who purchased Alkermes' stock during the Class Period. Alkermes' stock, however, remained artificially inflated as a result of false and misleading statements, and material omissions, by Defendants during the Class Period.

153. Following these reports, the next day the 6/13/17 Article was published and further highlighted the Company's deceptive marketing and lobbying efforts.

154. The market further reacted to this report, with shares of Alkermes stock declining to a low of $57.29, a decline of 7.1% from Alkermes' closing stock price of $61.66 on Friday, June 9, 2017, and a decline of 3.6% from Alkermes' closing stock price of $59.47 on Monday, June 12. Alkermes' stock, however, remained artificially inflated as a result of false and misleading statements, and material omissions, by Defendants during the Class Period.

155. Later that month, on June 27, 2017, the 6/27/17 Article was published and stated, among things, that Alkermes possessed previously nonpublic internal data showing that nearly 30% of Vivitrol users relapse within the 28-day time period after receiving their injections, meaning that taking Vivitrol does not completely bar relapse during that period.

156. The market reacted negatively to this news, with shares of Alkermes stock declining from a close of $58.30 per share on June 26, 2017, to a low of $57.05 on June 27 – a decline of 2.1%. Alkermes' stock, however, remained artificially inflated as a result of false and misleading statements, and material omissions, by Defendants during the Class Period.

157. Subsequently, on July 27, 2017, following the significant negative media coverage of Vivitrol described above, Alkermes announced in its Form 10-Q filing for the second fiscal quarter of 2017 that the Company had received a subpoena on June 22, 2017, relating to Vivitrol.

158. The market reacted negatively to this news, with shares of Alkermes stock declining from a close of $57.57 per share on July 26, 2017, to a low of $54.50 on July 27 – a decline of 5.3%. Alkermes' stock, however, remained artificially inflated as a result of false and misleading statements, and material omissions, by Defendants during the Class Period.

159. Then, the 10/18/17 Study was published on October 18, revealing in the first scientific test comparing Vivitrol to Suboxone that Vivitrol was only equally as effective at helping opioid addicts achieve abstinence, not better, as Defendants repeatedly claimed during the Class Period.

160. The market reacted negatively to this news, with shares of Alkermes stock declining from a close of $51.48 per share on October 17, 2017, to a low of $50.81 on October 18 – a decline of 1.3%. Alkermes' stock, however, remained artificially inflated as a result of false and misleading statements, and material omissions, by Defendants during the Class Period.

161. Following continued negative press coverage of Vivitrol, on November 6, 2017, Senator Harris announced the opening of an investigation into Alkermes' sales practices for Vivitrol.

162. The market reacted negatively to this news, with shares of Alkermes stock declining from a close of $50.99 per share on Friday, November 3, 2017, to a low of $48.56 on Monday, November 6 – a decline of 4.7%. Alkermes' stock, however, remained artificially inflated as a result of false and misleading statements, and material omissions, by Defendants during the Class Period.

163. Finally, during the trading day on November 14, 2017, the 11/14/17 Study was published, which demonstrated that not only was Vivitrol only as effective as Suboxone in helping opioid addicts achieve abstinence, but that it is actually less effective when accounting for the fact that Vivitrol patients must detox before receiving treatment.

164. The market reacted negatively to this news, with shares of Alkermes stock declining from a close of $49.17 per share on November 13, 2017, to a low of $47.58 on November 14 – a decline of 3.2%.

165. By concealing from investors the adverse facts detailed herein, Defendants presented a misleading picture of Alkermes' business and marketing tactics. When the truth about the

Company was revealed to the market, the price of Alkermes common stock substantially declined. Such decline removed the inflation from the price of Alkermes common stock, causing real economic loss to investors who had purchased Alkermes common stock during the Class Period.

166. The declines in the price of Alkermes common stock after the corrective disclosures came to light were a direct result of the nature and extent of Defendants' fraudulent misrepresentations being revealed to investors and the market. The timing and magnitude of the price declines in Alkermes common stock negate any inference that the loss suffered by Plaintiff and other Class members was caused by changed market conditions, macroeconomic or industry factors or Company-specific facts unrelated to Defendants' fraudulent conduct.

167. The economic loss, *i.e.*, damages, suffered by Plaintiff and other Class members was a direct result of Defendants' fraudulent scheme to artificially inflate the price of Alkermes common stock and the subsequent significant declines in the value of Alkermes common stock when Defendants' prior misrepresentations and other fraudulent conduct were revealed.

NO SAFE HARBOR

168. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the false statements alleged. Many of the statements herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, no meaningful cautionary statements identified important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew or had actual knowledge that the particular forward-looking statement was false, and/or the forward-

looking statement was authorized and/or approved by an executive officer of Alkermes who knew that those statements were false when made.

COUNT I

Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder (Against All Defendants)

169. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

170. During the Class Period, Defendants disseminated or approved the materially false and misleading statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and/or failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

171. Defendants: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of Alkermes stock during the Class Period.

172. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Alkermes stock. Plaintiff and the Class would not have purchased Alkermes stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements and/or omissions.

173. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their purchases of Alkermes stock during the Class Period.

COUNT II

Violations of Section 20(a) of the Exchange Act (Against the Individual Defendants)

174. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

175. The Individual Defendants acted as controlling persons of Alkermes within the meaning of Section 20(a) of the Exchange Act as alleged herein. By reason of their positions as officers and/or directors of Alkermes, and their ownership of Alkermes stock, the Individual Defendants had the power and authority to cause Alkermes to engage in the wrongful conduct complained of herein. By reason of such conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that this action is a proper class action, certifying Lead Plaintiff as Class representative under Rule 23 of the Federal Rules of Civil Procedure and Lead Plaintiff's counsel as Class Counsel;

B. Awarding compensatory damages in favor of Lead Plaintiff and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Lead Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Awarding Lead Plaintiff and the other members of the Class such other and further relief as may be just and proper under the circumstances.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

DATED: May 15, 2018

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Additional Counsel for Plaintiff

CERTIFICATE OF SERVICE

I, David A. Rosenfeld, certify that on May 15, 2018, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system for filing. Based on the records on file, the Clerk of the Court will transmit a Notice of Electronic Filing to the ECF registrants of record.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed this 15th day of May 2018, at Melville, New York.

/s/ David A. Rosenfeld
DAVID A. ROSENFELD